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I, JONNE YABSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002951548 for a patent by JEGANATH KRISHNAN as filed on 19 September 2002.

I further certify that the above application is now proceeding in the name of FLINDERS TECHNOLOGIES PTY. LTD. pursuant to the provisions of Section 113 of the Patents Act 1990.

WITNESS my hand this
First day of October 2003

J R Yabsley

JONNE YABSLEY
TEAM LEADER EXAMINATION
SUPPORT AND SALES

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Regulation 3.2

JEGANATH KRISHNAN

AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

for the invention entitled:

Implant Clamp and Method

The invention is described in the following statement:

IMPLANT CLAMP AND METHOD

This invention relates to a clamp for clamping an implant and to a method of fixing an implant.

In modern orthopaedic surgery various forms of implants are used. Some implants are cemented to a bone by means of a cement such as methyl methacrylate. It is desirable that the implant be held under pressure against the bone whilst the cement is cured in order to ensure that the implant is firmly bonded to the bone.

The object of the present invention is to provide a clamp which can be used for clamping an implant during curing of the cement. The same device can also be used to pressurise the cement mantle to allow deeper and more uniform penetration of cement through the bone tissue.

According to the present invention there is provided a clamp for clamping an implant to a bone, said clamp comprising a support member, means for coupling the support member to a bone, an arm pivotally connected to the support member, and an actuating member which is operable to cause rotation of the arm relative to the support member whereby the arm exerts pressure on an implant in order to force the implant into firm contact with the bone.

Preferably, the means for coupling comprises one or more pins which pass through bores in the support member.

Preferably further, the actuating member comprises a screw acting between one end of the arm and the support member.

Preferably further, the support means is generally in the form of a plate.

Preferably further, a number of bores are provided through the plate so that a plurality of pins can be used to securely connect the support member to a bone.

Preferably further, a pressure plate is mounted on the free end of the arm in order to engage the implant.

The invention also provides a method of fixing an implant to a bone comprising the steps of preparing a surface of the bone for receipt of an implant, coupling a clamping member to the bone adjacent to said surface, applying implant cement between the surface and the implant, actuating the clamp so that the implant is forced into engagement with the cement on the surface.

Preferably the method includes the step of curing the cement whilst the clamp is still operative.

Preferably further, the cement is cured with ultraviolet radiation.

The invention will now be further described with reference to the accompanying drawings, in which:

Figure 1 is a frontal view of an implant clamp;

Figure 2 is a side view of the implant clamp;

Figure 3 is a plan view of the implant clamp; and

Figure 4 schematically illustrates the use of the implant clamp.

Figures 1 to 3 illustrate an implant clamp 2 constructed in accordance with the invention. The clamp is particularly suited for use in knee replacement surgery. In that surgery, the top part of the tibia, i.e. the articular surface, is removed so as to define a flat

bone surface 4 against which an implant 6 can be cemented in position. The clamp 2 of the invention can be used to clamp the implant 6 against the surface 4 during curing of the implant cement.

The clamp 2 of the invention is made from a number of components which are arranged for easy disassembly for cleaning and sterilisation. It is preferred that the components are also made from stainless steel so that they can be autoclaved.

The clamp 2 comprises a support plate 10 from which projects an abutment block 12. Above the block 12 is a slot 14 which receives a clamp arm 16. The plate 10 includes a bore 18 through which a pivot shaft 20 passes. The pivot shaft 20 also passes through a hole 22 in the arm 16. As best seen in Figure 2, the arm 16 may include a number of adjacent holes 24 and 26, as shown in Figure 2, so as to provide adjustment of the pivot point of the arm 16 relative to the plate 10. Similarly, the plate 10 itself may include bores 28 and 30 to permit vertical adjustment of the pivot point of the arm 16 relative to the plate 10. As best shown in Figures 1 and 3, the end of the shaft 20 includes a tapered head 32 which assists in holding the shaft 20 in the selected bore through the plate 10.

The clamp includes a screw 34 having a head 36 which is relatively large so that it can be manually operated. The screw 34 passes through a threaded bore 38 in the arm 16 so that the lower end 40 of the screw abuts the top face 42 of the block 12.

In use, rotation of the screw 34 in the threaded bore 38 causes rotation of the arm 16 relative to the plate 10. The free end of the arm 16 is bifurcated at 44 and receives a mounting plate 46 of a pressure plate 48. The pressure plate 48 may comprise a semi-cylindrical shell having a diameter say of about 20mm and a length of say 50mm. The mounting plate 46 is preferably located at the centre of the pressure plate 48, as best seen in Figure 3. The mounting plate 46 is adjustably mounted relative to the arm 16 by means of a mounting bolt 49 which passes through aligned bores 50 and 52 in the arm 16 and plate 46 respectively. A nut 54 is used to fix the position of the mounting plate 46 relative to the arm 16.

As will be appreciated from Figure 2, alteration of the pressure plate 48 relative to the arm 16 can be used to change the position of the lowermost point 60 on the pressure plate 48 relative to the plate 10 both vertically and horizontally as indicated by lines 62 and 64. As will be explained below, the lowermost point 60 constitutes the point of contact with the upper surface of the implant 6. This enables fine adjustment of the position of the point of contact on the implant to enable it to be correctly aligned with the flat surface 4 of the tibia.

The plate 10 includes upper bores 66, intermediate bores 68 and lower bores 70. The bores are for receipt of arresting pins 72 which pass therethrough and are temporarily located in bores drilled in the tibia, as shown in Figure 4. It is preferred that the outermost lower bores 70 are inclined downwardly and inwardly at an angle of about 20° so as to provide a better mechanical fixing of the plate 10 to the tibia. The lower edge of the plate 10 includes a downward extension 74 which is provided with a plurality of central bores 76 for receipt of additional mounting pins if these are required.

In use of the device of the invention, the plate 10 is first securely fixed to the upper part of the tibia by the pins 72. Normally about four pins would be required for this purpose. The arm 16 can then be placed in position in the slot 14 and the shaft 20 can be located so as to form the pivotal connection. The clamping device can first be operated to pressurise a layer of cement applied to the flat surface 4 of the tibia. The implant 6 can then be located on the cement in its correct position relative to the tibia. The surgeon then operates the screw head 36 so as to apply a controlled downward force on the upper face of the implant 6 by appropriate adjustment of the pivotal mounting of the arm 16 relative to the plate and of the pressure plate 48 relative to the free end of the arm 16 the exact location of the point of contact of the pressure plate on the top surface of the implant 6 can be finally adjusted. Also, the screw head 36 enables the amount of downward force to be controlled. With the implant 6 firmly held in its correct position, ultraviolet radiation can then be used to cure the cement.

Many modifications will be apparent to those skilled in the art without departing from the spirit and scope of the invention.

DATED this 19th day of September, 2002

JEGANATH KRISHNAN
By his Patent Attorneys
DAVIES COLLISON CAVE